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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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18

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/211,715

Applicant(s)

AL-OB DIEI

Examiner

F. MOEZIE

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb. 8, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above, claim(s) 12-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 21-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-26 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) All b) ☐ Some\* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other

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## **DETAILED ACTION**

### **STATUS OF CLAIMS**

Claims 1-11, 21-26 are pending prosecution in this application. Claims 21- 23 have been joined with the earlier claims upon applicants request (see, below for explanation).

Claims 1-23, claims drawn to compounds, were restricted in paper no. 8, mailed 11/19/99. Applicant elected claims 1-11, with traverse, paper no. 10, received 01/24/00. The restriction requirement was made final in the Office action mailed 3/23/00, paper no. 11, wherein applicant was informed that the claims to the methods of use will be rejoined upon the indication of allowability for the respective compounds.

Claims 12-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10, filed 2.10/00.

### **COMPLIANCE WITH THE AMINO ACID SEQUENCE LISTING REQUIREMENTS**

Compliance with the Sequence Listing Requirements is incomplete.

**Note: Upon compliance with the requirements applicant must also amend the application to provide the SEQ ID NOS in THE SPECIFICATION (at least in the first occupance) in ALL EXAMPLES, TABLES and THE CLAIMS**

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It is noted that, for example, TABLE 5, and Examples do not comply with the requirements. Also none of the claims carry the SEQ ID NOS along with the sequence. See, for example in claim 7, second and the last sequences at pages 112 and 113 are to be identified by SEQ ID NOS: 105 and 108, respectively. However, they are not so identified. See, also the claims in the parent application.

**REJECTION - 35 U.S.C. 112, FIRST AND SECOND PARAGRAPHS**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 21-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Enablement is lacking regarding the how to make and use for the myriad of claimed peptides which are to "specifically inhibit the activity of Factor Xa". Which or what is the common core amino acid sequence that would elicit said function to the claimed peptides? .

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Foreman*, 230 USPQ 546 (Bd Apls 1986) at 547 the court recited eight factors:

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- 1) the quantity of experimentation necessary,
- 2) the amount of direction and guidance provided,
- 3) The presence or absence of working examples,
- 4) The nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art ‘
- 7) the predictability of the art, and
- 8) the breath of the claims.

Applicant fails to set forth “the common core” required in the peptide for eliciting the necessary function. Additionally, applicant fails to provide information allowing the skilled artisan to know when or under what circumstances a “the common core” is formed, isolated and can be used to perform its assigned function. The instant claims read on a myriad of unrelated peptides (having an immense number of negative limitations, particularly in case of claim 1).

Determination of a useful peptide containing unspecified “common core” for the same, necessitate an exhaustive search for determining the conditions under which the peptides would elicit the claimed function.

Claims 24 and 25, insofar as they read on a method of use in an in-vivo subject, are not enabled by the instant disclosure because there is/are no indication or showing that the claimed compounds do “specifically inhibit activity of Factor Xa” under in-vivo conditions, especially in a patient.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 and 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite and confusing as to what is being claimed. For example, there is no definition for what "B" could be ( page 103, line 23), however there are many pages (pp 104-108) for what it could not be!

In claim 2, page 105, line 15, the Markush Grouping for  $R_1$  is incorrect. The terminology "the group consisting of" should follow "selected from". The Markush language for  $R_2$  on page 109 is incomplete. The term "and" prior to the last Markush member is missing. At page 110, line 2, the terminology "selected from the group consisting of" is missing for following "is".

In claim 3, pages 110-112, there are many occurrences of improper Markush language which would have to be corrected.

In claim 9, the structure for  $-\text{Dah}(\text{CH}=\text{N}(\text{CH}_3)_2)$  is unclear and indefinite. What is the expanded structure for this peptide?

In claim 21, the position of attachment for "Me" in  $-\text{Pal}(\text{Me})-$  is indefinite and unclear.

All claims are indefinite as to what the "core peptide" is, which is required to illicit the claimed function. See, especially claim 11 in this regard and compare it with claim 10 peptides -

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no common core. Is applicant claiming more than one invention, wherein  $m=1$  (according to the generic formula, line 3 of claim 1)? See, the request made by applicant for including claims 21-23 with the instant claims under prosecution.

Complete review and correction of the claims is suggested.

Upon further consideration, the earlier immature withdrawal of the rejection of claims 1-11 under 35 U.S.C. 102 (a and/or b)/ 103 (a) over Brunck and Marlow is reinstated. Because this application is a CIP of the parent, the priority date does not extend beyond the filing date of the instant application, unless it can be shown that the claimed subject matter has been present in the earlier applications. Examiner has not been able to locate the parent files to the instant Application for the purposes of comparing the new matter entered into this CIP. Applicant is urged to clarify this matter in order to expedite the prosecution of this application. Note; Burnck patent has a priority that dates back to Dec. 15, 1993.

The rejection of claim 11 under 35 U.S.C. 101 is maintained for the reasons of record.

The Obviousness Double patenting rejection of the claims is maintained for the reasons of record.

#### **RESPONSE TO APPLICANTS' REMARKS**

Applicant's arguments filed July 26, 2000, paper no. 14, have been considered and found persuasive in-part.

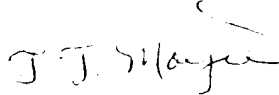
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Applicants' remarks regarding the inclusion of claims 21-23 in the claims being examined has been considered and found somewhat persuasive. These claims are currently examined along with Group I invention claims. It is noted that Claim 21 is also a peptide cited in claim 20, Group II invention, among other peptides. Deletion of this peptide from claim 20 is suggested. However, this request at this time casts a further shadow on the instantly prosecuted claims regarding the "common core" required to elicit the claimed activity.

Applicants' remarks regarding claims 24 and 25 have been considered. However, in the absence of representative examples showing the use as claimed, claims are not enabled.

Clearly, claim 1 is not enabled by the instant disclosure as the "common core" required for the function of the peptides remains questionable.

Any inquiry concerning this communication should be directed to F.T.Moezie at telephone number (703) 305-4508 - FAX (703)305-7401.

  
F.T. MOEZIE, P.D.  
PRIMARY EXAMINER  
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